Complete Summary

GUIDELINE TITLE

Transcutaneous bilirubin testing. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Kazmierczak S, Bhutani V, Gourley G, Kerr S, Lo S, Robertson A, Sena SF. Transcutaneous bilirubin testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 5-12. [74 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Jaundice in neonates (neonatal hyperbilirubinemia)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Screening

CLINICAL SPECIALTY

Family Practice
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To examine the application of evidence-based medicine (EBM) to the form of diagnostic testing known as point-of-care testing (POCT)

  Note: For the purpose of this document, POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POCT refers to any testing performed outside of the traditional, core or central laboratory."

- To systematically review and synthesize the available evidence on the effectiveness of POCT, with specific focus on outcomes in the areas of:
  1. Patient/health
  2. Operational/management
  3. Economic benefit
- To evaluate the available literature and identify those studies that clearly demonstrate the utility of transcutaneous point-of-care bilirubin testing compared with traditional clinical laboratory–based measurement

TARGET POPULATION

Healthy, term infants with hyperbilirubinemia

INTERVENTIONS AND PRACTICES CONSIDERED

Transcutaneous bilirubin testing

MAJOR OUTCOMES CONSIDERED

- Clinical outcomes such as length of stay and readmission rates
- Accuracy and cost-effectiveness of transcutaneous bilirubin measurement

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For a specific clinical use, pertinent clinical questions were formulated and key search terms were ascertained for the literature search. Searches were conducted on MEDLINE or PubMed and were supplemented with the use of the National Guideline Clearinghouse, the Cochrane Group, or evidence-based medicine (EBM) reviews. Additionally, authors' personal article collections were used. Acceptable citations were limited to peer-reviewed articles with abstracts, those published in English, and those involving human subjects.

To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Abstracts identified by the literature searches were reviewed by 2 individuals to determine initial eligibility or ineligibility for full-text review, using Form 1 (Appendix A - see the "Availability of Companion Documents" field). If there was not consensus, then a third individual reviewed the abstract(s). To be included in the full systematic review of the clinical question, articles selected for full text

review were examined for at least 1 relevant outcomes measurement. The systematic review consisted of creating evidence tables using Form 2 (Appendix A - see the "Availability of Companion Documents" field) that incorporated the following characteristics:

1. Study design—Prospective or retrospective, randomized, and controlled, patient inclusion/exclusion criteria, blinding, number of subjects, etc.
2. Appropriateness of controls
3. Potential for bias (consecutive or nonconsecutive enrollment)
4. Depth of method description—full-length report or technical brief
5. Clinical application—screening, diagnosis, management
6. Specific key outcomes and how they were measured
7. Conclusions are logically supported

For the assessment of study quality, the general approach to grading evidence developed by the US Preventive Services Task Force was applied (see the "Rating Scheme for the Strength of the Evidence" field). Once that was done, an assessment of study quality was performed, looking at the individual and aggregate data at 3 different levels using Forms 3 and 4 (Appendix A - see the "Availability of Companion Documents" field). At the first level, the individual study design was evaluated, as well as internal and external validity. Internal validity is the degree to which the study provides valid evidence for the populations and setting in which it was conducted. External validity is the extent to which the evidence is relevant and can be generalized to populations and conditions of other patient populations and point-of-care testing (POCT) settings.

The synthesis of the volume of literature constitutes the second level, Form 5 (Appendix A - see the "Availability of Companion Documents" field). Aggregate internal and external validity was evaluated, as well as the coherence/consistency of the body of data. How well does the evidence fit together in an understandable model of how POCT leads to improved clinical outcome? Ultimately, the weight of the evidence about the linkage of POCT to outcomes is determined by assessing the degree to which the various bodies of evidence (linkages) "fit" together. To what degree is the testing in the same population and condition in the various linkages? Is the evidence that connects POCT to outcome direct or indirect? Evidence is direct when a single linkage exists but is indirect when multiple linkages are required to reach the same conclusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The field of point-of-care testing (POCT), diagnostic testing conducted close to the site of patient care, was divided into disease- and test-specific focus areas. Groups of expert physicians, laboratorians, and diagnostic manufacturers in each focus area were assembled to conduct systematic reviews of the scientific literature and prepare guidelines based on the strength of scientific evidence linking the use of POCT to patient outcome.

Final guidelines were made according to Agency for Healthcare Research and Quality (AHRQ) classification (see the "Rating Scheme for the Strength of the Recommendations" field). The guidelines are evidence based and require scientific evidence that the recipients of POCT experience better health outcomes than those who did not and that the benefits are large enough to outweigh the risks. Consensus documents are not research evidence and represent guidelines for clinical practice, and inclusion of consensus documents was based on the linkages to outcomes, the reputation of the peer organization, and the consensus process used to develop the document. Health outcomes, e.g., benefit/harm, are the most significant outcomes in weighing the evidence and drafting guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

The guideline developers reviewed published cost analyses.

No studies have been performed to evaluate the actual costs associated with implementation of transcutaneous bilirubin measurements. Some studies suggest that the increased cost of transcutaneous bilirubin measurements is offset by a decrease in the need for serum bilirubin measurements. One set of researchers attempted to evaluate the costs associated with transcutaneous bilirubin measurements by estimating the impact of transcutaneous bilirubin measurements on hospital charges. They found that there were decreased charges as a result of fewer readmissions of newborns because of hyperbilirubinemia. However, the decrease in readmissions was offset by increased charges associated with transcutaneous bilirubin measurements and an increased number of newborns treated with phototherapy before discharge after the introduction of transcutaneous measurements. The net result was a small but statistically insignificant increase in charges after the introduction of transcutaneous bilirubin measurements. Because these authors report charges associated with implementation of transcutaneous bilirubin measurements, it is still not clear what the implementation of transcutaneous measurements does to actual costs.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were presented in open forum at the American Association for Clinical Chemistry (AACC) Annual Meeting (Los Angeles, CA, USA) in July 2004. Portions of these guidelines were also presented at several meetings between 2003 and 2005. Participants at each meeting had the ability to discuss the merits of the guidelines and submit comments to the National Academy of Clinical Biochemistry (NACB) Web site for formal response by the NACB during the open comment period from January 2004 through October 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I—III) and grades of the recommendation (A, B, C, I) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) evidence-based practice for point-of-care testing sponsored by the NACB* have been divided into individual summaries covering disease- and test-specific areas. In addition to the current summary, the following are available:

- Chapter 1: Management
- Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes
- Chapter 4: Coagulation
- Chapter 5: Critical Care
- Chapter 6: Diagnosis and Management of Diabetes Mellitus
- Chapter 7: Drugs and Ethanol
- Chapter 8: Infectious Disease
- Chapter 9: Occult Blood
- Chapter 10: Intraoperative Parathyroid Hormone
- Chapter 11: pH Testing
- Chapter 12: Renal Function Testing
- Chapter 13: Reproductive Testing

Does transcutaneous bilirubin measurement improve clinical outcome, shorten length of stay, or decrease readmission rate for newborns with hyperbilirubinemia, compared with measurement of bilirubin in serum? (Literature Search 3 – Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 6. Assessment of hyperbilirubinemia with use of transcutaneous bilirubin measurements may have utility in decreasing readmission rate of newborns with hyperbilirubinemia and monitoring bilirubin concentrations in newborns. To date, only 1 study has been published that addresses this issue. Further evidence is needed to evaluate whether transcutaneous bilirubin measurements improve clinical outcome, shorten length of stay, or decrease the

readmission rate for newborns with hyperbilirubinemia.
Strength/consensus of recommendation: I
Level of evidence: III (clinical experience, descriptive studies, and opinion)

Is there an optimum frequency, timing, or site of transcutaneous bilirubin measurements that results in best agreement with bilirubin measurements performed using serum? (Literature Search 4 – Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 7. Transcutaneous bilirubin measurements performed on the forehead or sternum are preferable to other sites and provide similar correlation with bilirubin measurements performed in serum when infants have not been exposed to sunlight or phototherapy. Bilirubin concentrations should be assessed by measurement of total bilirubin in serum or transcutaneous bilirubin measurements within the first 24 h after birth in all infants who are jaundiced. The need for and timing of repeated transcutaneous or serum bilirubin measurements should be assessed with nomograms according to the postnatal age and bilirubin concentration.
Strength/consensus of recommendation: B
Level of evidence: II and III (well-designed correlation trials, clinical experience, and consensus opinion)

Is the measurement of bilirubin by use of a transcutaneous method contraindicated for use in newborns who are undergoing phototherapy, premature infants, or newborns who are ill? (Literature Search 5 – Refer to Appendix B - see the "Availability of Companion Documents" field).

Guideline 8. Transcutaneous bilirubin measurements should not be performed on infants undergoing phototherapy. The guideline developers also note that light exposure of infants who are discharged may also adversely affect the utility of transcutaneous measurements. The effect of gestational age on transcutaneous bilirubin measurements is less clear. Some reports suggest limiting the use of transcutaneous bilirubin measurements to newborns <30, 32, or 34 weeks' gestation, whereas others suggest no effect of gestational age. There are too few studies available that address the effect of underlying illness in newborns and its effect on use of transcutaneous bilirubin measurements.
Strength/consensus of phototherapy recommendation: C
Level of evidence: II and III (well-designed clinical trials, descriptive studies, and consensus opinion)
Strength/consensus of premature/gestational age recommendation: C
Level of evidence: II (well-designed clinical trials, descriptive studies)
Strength/consensus of underlying illness recommendation: I

Are transcutaneous bilirubin measurements associated with decreased blood sampling compared with serum bilirubin measurements? Do transcutaneous bilirubin measurements decrease the incidence of complications associated with blood collection such as infection or osteomyelitis? (Literature Search 6 - Refer to Appendix B - see the "Availability of Companion Documents" field).

Guideline 9. There is insufficient evidence available to judge the impact of transcutaneous bilirubin measurements on number of blood samples collected from newborns. Whether there is any effect on complications of blood collection

such as infection or osteomyelitis has not been adequately studied.
Strength/consensus of recommendation: I

How does the accuracy of transcutaneous bilirubin measurements compare with total bilirubin measured in serum? (Literature Search 7- Refer to Appendix B - see the "Availability of Companion Documents" field).

Guideline 10. The guideline developers cannot recommend use of the ColorMate III (Chromatics Color Sciences International Inc., New York, NY) bilirubinometer, because of the limited number of published articles describing the performance of this instrument. Evaluation of jaundice with the Air-Shields or BiliChek seems to provide accuracy similar to that of serum bilirubin measurements. The BiliChek and Air-Shield have the advantage, compared with the ColorMate III, of not requiring a baseline measurement. Finally, the guideline developers do not recommend assessment of bilirubin with use of the Ingram icterometer (Thomas A. Ingram and Co, Birmingham, England; distributed in the United States by Cascade Health Care Products, Salem, OR), because of its reliance on observer visualization of depth of yellow color of the skin.
Strength/consensus of recommendation: B
Level of evidence: II (well-designed correlation trials, clinical experience, descriptive studies, and opinion)

Is measurement of bilirubin with a transcutaneous device more cost-effective compared with bilirubin measurements performed in the clinical laboratory? (Literature Search 8 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 11. There is insufficient evidence to evaluate the cost-effectiveness of transcutaneous bilirubin measurements.
Strength/consensus of recommendation: I
Level of Evidence: III (descriptive studies, opinion)

Definitions:

Levels of Evidence

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Strength of Recommendations

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

It is hoped that these guidelines will be useful for those implementing new testing, as well as those reviewing the basis of current practice. These guidelines should help sort fact from conjecture when testing is applied to different patient populations and establish proven applications from off-label and alternative uses of point-of-care testing (POCT). These guidelines will also be useful in defining mechanisms for optimizing patient outcome and identify areas lacking in the current literature that are needed for future research.

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

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Transcutaneous bilirubin measurements should not be performed on infants undergoing phototherapy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The material in this monograph represents the opinions of the editors and does not represent the official position of the National Academy of Clinical Biochemistry or any of the cosponsoring organizations.
- Point-of-care testing (POCT) is an expanding delivery option because of increased pressure for faster results. However, POCT should not be used as a core laboratory replacement in all patient populations without consideration of the test limitations and evaluation of the effect of a faster result on patient care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Kazmierczak S, Bhutani V, Gourley G, Kerr S, Lo S, Robertson A, Sena SF. Transcutaneous bilirubin testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 5-12. [74 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Preface and introduction. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. i-xvi.

- Appendix A: NACB LMPG data abstraction forms. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 149-153.
- Appendix B: literature searches. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 154-186.

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

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